

## **REMARKS**

This submission is being filed concurrently with a Request for Continued Examination. A Notice of Appeal and Request for Pre-Appeal Brief Conference was filed on May 1, 2007. Thereafter, a Notice of Panel Decision from Pre-Appeal Brief Review was mailed on May 23, 2007. Accordingly, the Request for Continued Examination, along with this submission, is proper under 37 C.F.R. § 1.114(d).

After entry of the present amendment, claims 1-114 will be pending, of which claim 1 is currently amended. Support for this amendment can be found throughout the as-filed specification, claims and drawings, for example, at paragraphs [0068] and [0070]. No new matter is being added upon entry of this amendment. Applicants' amendment herein is not a concession or admission that original claim 1 is unpatentable. Applicants reserve the right to prosecute the subject matter of original claim 1 in a continuing application.

### **I. Rejections Under 35 U.S.C. § 103**

Claims 1-11, 55-64, 66, 68-77 and 111-114 stand rejected under 35 U.S.C. § 103 as allegedly being unpatentable over U.S. Pat. App. No. 2004/0209354 to Mathies et al., ("the Mathies application") in view of U.S. Pat. App. No. 2004/0037739 to McNeely et al. ("the McNeely application"). Applicants respectfully submit that this rejection is improper because the office action does not set forth the basic requirements of a *prima facie* case of obviousness that is required by MPEP § 2143.

Applicants have previously addressed these rejections in their Pre-Appeal Brief Request For Review, filed May 1, 2007. Applicants reiterate these arguments in this submission and provide additional argument to supplement their previously advanced arguments.

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the reference itself or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success

must both be found in the prior art, and not based on applicant's disclosure. MPEP § 2143; In re Vaeck, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).<sup>1</sup> Applicants respectfully submit that because the February 7, 2007 Office Action (the "Office Action") does not set forth all of these elements, the rejection should be reconsidered and withdrawn.

**A. The Mathies and McNeely Applications Do Not Render Applicants' Invention Obvious**

The Office Action alleges that it would have been obvious to replace the capillary electrophoresis system disclosed in the Mathies application with a detection system dependent on the use of microarrays and to utilize a system of microarrays to detect analytes following purification in the apparatus disclosed by the Mathies application. Applicants respectfully assert that there is no motivation to substitute a microarray for the capillary electrophoresis system of the Mathies application.

It is known in the art that capillary electrophoresis comprises placing one or more species into a conduit that spans two electrodes and then applying an electric field so as to physically separate the species on the basis of the species' **size** and **electric charge**. Information regarding the **size** of a given species is then obtained by determining the distance a given species traveled within the conduit under the electric field.

By contrast, microarrays are "collection[s] of probes synthesized, attached, or dispersed on a substrate," (see pending Application at [0035]) and distinguish between different species based on differences in the species' **structures** and the species' ability to bind to specifically-structured probes located within the microarray. The microarray is then inspected to determine which species have bound to which probes so as to obtain information regarding the **structure of the sample molecules** (*e.g.*, the sequence of nucleotides comprising a DNA sample) comprising a given sample. By contrast, capillary electrophoresis, as discussed, provides information regarding the **size of sample molecules**.

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<sup>1</sup> Applicants recognize that the Supreme Court's decision in KSR Int'l Co. v. Teleflex Inc., 550 U.S. \_\_\_\_ (April 30, 2007), cast into doubt the Federal Circuit's application in that case of the "teaching-suggestion-motivation" test for obviousness under 35 U.S.C. § 103. See KSR Slip Opinion at 11 ("We begin by rejecting the rigid approach of the Court of Appeals.") In any event, Applicants submit that the instant invention is not obvious in light of the Mathies or McNeely applications, either individually or in combination, under the teaching-suggestion-motivation analysis or under any new obviousness analysis adopted by the Federal Circuit and/or the USPTO in light of the KSR decision.

Accordingly, Applicants submit that capillary electrophoresis and microarrays (a) function by wholly different mechanisms; and (b) provide qualitatively different information regarding processed samples. Because capillary electrophoresis and microarrays function by different mechanisms and provide different information (sample **size** and sample **structure**, respectively), Applicants submit there is no motivation to combine the Mathies and McNeely applications and perform the substitution suggested in the Office Action. See MPEP § 2143.01; In re Mills, 916 F.2d 680, 16 USPQ 2d 1430 (Fed. Cir. 1990) (the mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination). Because there is no motivation to perform the substitution, the Office Action does not establish a *prima facie* case of obviousness, and claim 1 should therefore be allowed. See MPEP § 2143; In re Vaeck, 947 F.2d 488.

Second, Applicants respectfully disagree with the Office Action's assertion that "it would have been obvious to utilize a system of microarrays to detect analytes following purification in the apparatus disclosed by [the Mathies application]." (Office Action at 4.) Applicants submit that the Mathies and McNeely applications, either individually or in combination, do not teach the combination and connection of these elements within an integrated device, such as a microfluidic chip. MPEP § 2143.02.

As the Office Action recognizes, the Mathies application does not teach the use of **microarrays** or, moreover, teach an **integrated device**, such as a microfluidic chip, that comprises a **microarray** connected to a porous polymer monolith. (See Office Action at 3 ("Mathies, however, teaches that detection is accomplished using capillary electrophoresis **instead of a microarray**.")) (emphasis added). Similarly, the McNeely reference contains no discussion of integrating microarrays and a functionalized porous polymer monolith into a single, integrated device. To the extent the Office Action alleges that capillary electrophoresis systems and microarrays are interchangeable, Applicants refer the Examiner to the previous discussion in this submission that highlights the structural and functional differences between capillary electrophoresis and microarrays. Accordingly, Applicants submit that the instant invention is technically distinct from the Mathies and McNeely applications and that those references are therefore inapposite.

**B. The Presently Amended Claims Are Non-Obvious In Light of The Other Cited References**

Even accepting for the sake of argument only that there is some technical concordance between Applicants' invention and the Mathies and McNeely applications (and Applicants make no such concession), the presently amended claims are nevertheless nonobvious in light of the references cited in the Office Action. Applicants submit that none of the four references cited are apposite to Applicants' amended claim 1. Neither the Mathies application, the McNeely application, the Werner application (US 2002/0168652), nor the Christel reference (U.S. 6,363,871) teach, suggest, or otherwise motivate one of ordinary skill in the art to provide a microfluidic chip comprising, *inter alia*, **a microarray situated within at least one microchannel, the microchannel being characterized as having at least one cross-sectional dimension of less than about 10 microns.**

First, Mathies teaches, at paragraph [0101], channels having a depth of 36 microns. McNeely teaches, at paragraph [0084], channels having a depth of 15 microns or, more preferably 25 microns. The Werner application contains no discussion of microchannel dimensions. Finally, the Christel reference, **col. 6, ll. 8-9**, teaches channels having dimensions that are "typically" from 10 to 1000 microns in depth. Accordingly, none of the cited references teaches, suggests, or otherwise motivates microarrays situated within at least one microchannel having the dimensional limitations of Applicants' microchannels.

Moreover, at least one of the cited references in fact **teaches away** from the use of microchannels having at least one cross-sectional dimension of less than 10 microns. This teaching away significantly favors finding Applicants' invention non-obvious. See MPEP § 2145.X.D.1 "[a] prior art reference that 'teaches away' from the claimed invention **is a significant factor to be considered** in determining obviousness"); Ecolochem, Inc. v. Southern Cal. Edison Co., 227 F.3d 1361, 1374-1375 (Fed. Cir. 2000) (concluding that a determination of obviousness was erroneous where district court failed to properly account for "teaching away" effect of particular cited reference).

Despite the Office Action's reliance on the McNeely reference as a basis for rejecting Applicants' claims (see Office Action at 2-19), Applicants observe that the McNeely reference in fact teaches away from Applicants' claimed invention. The McNeely reference

states, at paragraph [0084] that 15 microns is the minimum lower depth for microchannels because “**reducing the chamber heights causes problems if the height goes below about a certain height.**” Accordingly, by counseling **against** the use of channels of less than 15 micron depth, McNeely teaches away from Applicants’ less than 10 micron-depth channels, thus implying that Applicants’ invention is non-obvious in light of McNeely. MPEP § 2145. Because McNeely **teaches away** from Applicants’ invention, Applicants submit that the McNeely application should not be given weight in the obviousness determination. For the previously-discussed reasons, the other cited references, individually or in combination, do not cure the shortcomings of the McNeely reference.

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Accordingly, Applicants submit that none of the cited references, whether individually or in combination with the other cited references, teach any of Applicants’ microfluidic chips as presently claimed. Applicants respectfully submit that the Office Action fails to establish a *prima facie* case of obviousness, and that the claims are allowable. See MPEP § 2143; In re Vaeck, 947 F.2d 488. Applicants submit that because the rejection of independent claim 1 is improper and should be withdrawn, all dependent claims related to claim 1 should be allowed. See In re Fine, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) (any claim depending from an independent claim nonobvious under 35 U.S.C. § 103 is itself nonobvious.)

**DOCKET NO.:** SNL-0004  
**Application No.:** 10/701,097  
**Office Action Dated:** February 7, 2007

**PATENT  
SUBMISSION FILED WITH  
REQUEST FOR CONTINUED EXAMINATION  
UNDER 37 CFR § 1.114**

**II. Conclusion**

Applicants respectfully request that the Examiner:

- (1) enter the amendments to the claims,
- (2) reconsider and withdraw the rejections of the claims; and
- (3) pass claims 1-114 to allowance.

Applicants believe the foregoing constitutes a complete response to the Office Action and submit that all pending claims are in condition for ready allowance. An early Office Action to that effect is, therefore, earnestly solicited. Should the Examiner have any questions or require any additional information, he is requested to contact the undersigned attorney at 215-568-3100.

Respectfully submitted,

Date: August 29, 2007

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